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Steffen Goletz

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EXAMINER

SANG, HONG

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1643

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/522,087	Applicant(s) GOLETZ ET AL.	
	Examiner HONG SANG	Art Unit 1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 4-6, 8, 12 and 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/16/05, 3/21/05 and 12/3/07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

RE: Goletz et al.

1. Applicant's election of Group I (claims 1-3, 7, and 9-11) and species election of antibody A76-A/C7 and cell lines (including cell lysate and/or cellular supernatant thereof) in the reply filed on 8/4/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-13 are pending. Claims 4-6, 8 and 12-13 are withdrawn from further consideration as being drawn to non-elected inventions.
3. Claims 1-3, 7 and 9-11 are under examination. Due to species election, claim 7 is examined to the extent that the antibody is A76-A/C7, and claim 3 is examined to the extent that the MUC1 molecule or mixture thereof is recovered from cell lines, cell lysate and/or cellular supernatant thereof.

Priority

4. Receipt is acknowledged of papers filed under 35 U.S.C. 119 (a)-(d) based on an application filed in European Patent Office on 7/22/02. Applicant has not complied with the requirements of 37 CFR 1.63(c), since the oath, declaration or application data sheet does not acknowledge the filing of any foreign application. A new oath, declaration or application data sheet is required in the body of which the present application should be identified by application number and filing date.

Information Disclosure Statement

5. The information disclosure statements (IDS) filed on 3/16/2005, 3/21/2005 and 12/3/2007 have been considered. Signed copies have been attached hereto.

Drawings

6. The drawings are objected to because of minor informalities. The "Figure D(2)" on the drawing sheet 11 of 16 should be "Figure 5D(2)". The number "5" is missing.

Specification

7. The disclosure is objected to because of the following informalities. The Brief Description of the Drawings does not reference each of the Figures. The Brief Description should be amended to reference Figures 3A and Figure 3B. Correction is required.

Claim Objections

8. Claims 7 and 9-11 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). For compact prosecution, claims 7 and 9-11 are interpreted as being dependent from claim 1.

9. Claims 9-11 are objected to for being dependent from withdrawn claims.

10. Claims 9-11 are objected to because the claims contain non-elected inventions, for example, formulating the cell, the cell lysate or the antibody.

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Claim Rejections - 35 USC § 112, 2nd paragraph and 35 USC § 101

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claim 11 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11 provides for the use of a MUC1 molecule, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

MPEP states “Attempts to claim a process without setting forth any steps involved in the process generally raises an issue of indefiniteness under 35 U.S.C. 112, second paragraph. For example, a claim which read: “A process for using monoclonal antibodies of claim 4 to isolate and purify human fibroblast interferon.” was held to be indefinite because it merely recites a use without any active, positive steps delimiting how this use is actually practiced. Ex parte Erlich, 3 USPQ2d 1011 (Bd. Pat. App. & Inter. 1986)”. See MPEP 2173.05(q).

Claim 11 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper

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definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112, 1st paragraph

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 7 and 9-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, because the specification does not provide evidence that the claimed antibodies (see claim 7) are (1) known and readily available to the public; (2) reproducible from the written description.

It is unclear if cell lines which produce antibodies having the exact chemical identity of A76-A/C7, VU-11E2, VU-11D1, BC4E549, VU-12E1, VU-3D1 and b-12 are known and publicly available, or can be reproducibly isolated without undue experimentation. Therefore, a suitable deposit for patent purposes is suggested. Without a publicly available deposit of the above cell line, one of ordinary skill in the art could not be assured of the ability to practice the invention as claimed. Exact replication of: (1) the claimed cell line; (2) a cell line which produces the chemically and functionally

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distinct antibody claimed; and/or (3) the claimed antibody's amino acid or nucleic acid sequence is an unpredictable event.

For example, very different V_H chains (about 50% homologous) can combine with the same V_K chain to produce antibody-binding sites with nearly the same size, shape, antigen specificity, and affinity. A similar phenomenon can also occur when different V_H sequences combine with different V_K sequences to produce antibodies with very similar properties. The results indicate that divergent variable region sequences, both in and out of the complementarity-determining regions, can be folded to form similar binding site contours, which result in similar immunochemical characteristics. [FUNDAMENTAL IMMUNOLOGY 242 (William E. Paul, M.D. ed., 3d ed. 1993)]. Therefore, it would require undue experimentation to reproduce the claimed antibodies A76-A/C7, VU-11E2, VU-11D1, BC4E549, VU-12E1, VU-3D1 and b-12. Deposit of the hybridoma would satisfy the enablement requirements of 35 U.S.C. § 112, first paragraph. See, 37 C.F.R. 1.801-1.809.

If the deposit is made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposited material will be irrevocably removed upon the grant of a patent on this application. This requirement is necessary when deposits are made

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under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

If the deposit is not made under the provisions of the Budapest Treaty, then in order to certify that the deposits comply with the criteria set forth in 37 CFR 1.801-1.809 regarding availability and permanency of deposits, assurance of compliance is required. Such assurance may be in the form of an affidavit or declaration by applicants or assignees or in the form of a statement by an attorney of record who has the authority and control over the conditions of deposit over his or her signature and registration number averring:

(a) during the pendency of this application, access to the deposits will be afforded to the Commissioner upon request:

(b) all restrictions upon the availability to the public of the deposited biological material will be irrevocably removed upon the granting of a patent on this application:

(c) the deposits will be maintained in a public depository for a period of at least thirty years from the date of deposit or for the enforceable life of the patent of or for a period of five years after the date of the most recent request for the furnishing of a sample of the deposited biological material, whichever is longest; and

(d) the deposits will be replaced if they should become nonviable or non-replicable.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing

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the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

If a deposit is made after the effective filing date of the application for patent in the United States, a verified statement is required from a person in a position to corroborate that the biological material described in the specification as filed is the same as that deposited in the depository, stating that the deposited material is identical to the biological material described in the specification and was in the applicant's possession at the time the application was filed.

Applicant's attention is directed to In re Lundak, 773 F.2d. 1216, 227 USPQ 90 (CAFC 1985) and 37 CFR 1.801-1.809 for further information concerning deposit practice.

Claim Rejections - 35 USC § 112, 1st paragraph

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of a MUC1 molecule for producing a pharmaceutical composition for the treatment of tumors, does not reasonably provide enablement for the use of a MUC1 molecule for producing a pharmaceutical composition for the prevention of tumors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)).

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in In re Wands, 8 USPQ2d 1400 (CA FC 1988). Wands states at page 1404,

"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The nature of the invention

Claim 11 is drawn to the use of a MUC1 molecule for producing a pharmaceutical composition for the treatment or prevention of tumors.

The invention is in a class of invention, which the CAFC has characterized as "the unpredictable arts such as chemistry and biology." Mycogen Plant Sci., Inc. v.

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Monsanto Co., 243 F.3d 1316, 1330 (Fed. Cir. 2001).

The breadth of the claims

Claim 11 encompasses using the claimed MUC1 molecules for treatment and prevention of any tumors.

Quantity of experimentation

The quantity of experimentation in this area is extremely large in view of the breadth of the claim.

The unpredictability of the art and the state of the prior art

No material has been found to date that has been shown to or would be expected to prevent cancer, and there is no working example, prior art, or any evidence that would provide the skilled artisan with any predictable guidance to use the claimed invention, it would be reasonable to conclude the claimed invention is not enabled.

Reasonable guidance with respect to preventing any cancer relies on quantitative analysis from defined populations that have been successfully pre-screened and are predisposed to particular types of cancer. This type of data might be derived from widespread genetic analysis, cancer clusters, or family histories. The essential element towards the validation of a preventive therapeutic is the ability to test the drug on subjects monitored in advance of clinical cancer and link those results with subsequent histological confirmation of the presence or absence of disease. This irrefutable link

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between antecedent drug and subsequent knowledge of the prevention of the disease is the essence of a valid preventive agent. Further, a preventive administration also must assume that the therapeutic will be safe and tolerable for anyone susceptible to the disease.

The art teaches that compositions comprising some tumor associated antigens are effective in treatment of cancer through generation of immunogenic response to the tumor antigen (see for example, Komenaka et al., Clinics in Dermatology, 2004, 22: 251-265, page 257). However, nowhere in the art does it show that tumor antigens are effective at preventing cancer. Evans *et al* (Q. J. Med 1999: 92: 299-307) teach that vaccines against cancer are not fully established, and it is stated that adjuvant therapy to prevent or delay disease still needs experimentation. Evans *et al* further state that such cancer vaccines are at best used as a therapeutic and not as a prophylactic and that *"the notion that cancer vaccines will replace standard therapeutic strategies in malignant disease still belongs to the realm of fiction"* (see page 303 last paragraph).

Heretofore the art has only recognized the treatment of a cancer.

Working examples

The specification teaches production of immunostimulatory MUC1 carrying the MUC1 tumor epitope for vaccination (see Example 5A) and treating T-cells with purified secretory MUC1 carrying the MUC tumor epitopes (see Example 5B). The specification discloses in vitro tests as to the tumor-specific cytotoxicity (see Example 7). The specification does not teach treating cancer using any MUC1 antigens.

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Guidance in the specification

The specification provides insufficient guidance and objective evidence to indicate to one of skill in the art that the administration of the claimed MUC1 would be enabling to prevent cancer

Level of skill in the art

The level of skill in the art is deemed to be high.

Conclusion

Thus given the broad claims in an art whose nature is identified as unpredictable, the unpredictability of the art, the large quantity of research required to define these unpredictable variables, the lack of guidance provided in the specification, the absence of a working example and the negative teachings in the prior art balanced only against the high skill level in the art, it is the position of the examiner that it would require undue experimentation for one of skill in the art to perform the method of the claim as broadly written.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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18. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Snijdwint et al. (Cancer Immunol. Immunother., 1999, 48:47-55), as evidenced by Ryuko et al. (Tumor Biology, 2000, 21, 197-210, IDS).

Snijdwint et al. teach isolation of MUC1 mucin preparation from supernatant of the breast cancer cell line ZR-75-1 cultured for 5 days in serum-free medium, the isolation and purification was done on the basis of molecular size and affinity binding with MUC1 mAb 139H2 (see page 48, column 1, 1st paragraph). Snijdwint et al. disclose that the preparation of MUC1 mucin isolated from the supernatant of the breast cancer cell line ZR-75-1 were tested on PBMC of 3 healthy women and 12 ovarian cancer patients, and no significant effects were seen in the 3 healthy women, in 3 of the ovarian cancer patients a significant stimulating effect was seen (see page 49, column 2, 2nd paragraph, and Figure 3). The MUC1 mAb 139H2 appears to have the recited properties as evidenced by Ryuko et al. (see Figure 2).

The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the antibody of the prior art does not have the recited properties. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed antibodies are different from those taught by the prior art and to establish patentable differences. See *In re Best* 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray* 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

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Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. Claims 1-3, 7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Snijdewint et al. (Cancer Immunol. Immunother., 1999, 48:47-55), in view of Ryuko et al. (Tumor Biology, 2000, 21, 197-210, IDS), Chu et al. (US 4,939,240, Date of Patent: 7/3/1990), and Robertson et al. (US 7,402,403B1, Date of Patent: 7/22/2008, earliest effective filing date 5/11/1999).

The teachings of Snijdewint et al. have been set forth above as they apply to claims 1-3 (see paragraph 18).

Snijdewint et al. do not teach isolating MUC1 molecule with the antibody A76-A/C7 and further formulating the MUC1 molecule in a pharmaceutically acceptable form or diagnostically applicable form. However, these deficiencies are made up for in the teachings of Ryuko, Chu and Robertson et al.

Ryuko et al. teach characterization of a new MUC1 monoclonal antibody (VU-2-G7) as well as several known antibodies including A76-A/C7 which are directed to the glycosylated PDTR sequence of MUC1 (see abstract). Ryuko et al. disclose the epitopes to which these antibodies bind, and their reactivity patterns with a variety of synthetic nonglycosylated and glycosylated MUC1 peptides (20-mer and 60-mer MUC1 triple tandem repeat peptides, 60-mer 3M GalNAc and 60-mer 9M GalNAc, and

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modified MUC peptides) (see Table 1 and Figure 2). Ryuko et al. teach that the tested antibodies including A76-A/C7 and 139H2 react with all the MUC1 expressing cancer cell lines (see page 204, column 2, and Figure 4). Ryuko et al. teach that the antigen of VU-2-G7, 3M GalNac, may be the choice MUC1 glycopeptide for active immunotherapy (see page 209, last paragraph).

Chu et al. teach isolation and purification of ductal carcinoma antigen from cancer patients using a monoclonal antibody and further formulation of said antigen in an appropriate carrier e.g. saline, with or without human albumin at an appropriate dosage for administration to a patient in a vaccine formulation (see column 14, lines 54-66 and column 30, lines 14-48).

Robertson et al. provide a preparation comprising a human MUC1 protein which MUC1 protein manifests all the antigenic characteristic of a MUC1 protein obtained from the bodily fluids of a patient with advanced breast cancer (see column 7, lines 4-8). Robertson et al. teach that such preparation can be used to detect autoantibodies specific to MUC1 (see column 7, lines 17-31). Robertson et al. teach assay kits suitable for performing the methods for the detection of autoantibodies, including samples of the tumor marker antigens and means for contacting the sample to be tested with a sample of the antigen (see column 8, lines 13-18). Robertson et al. teach a method of isolation of ABC MUC1 from advanced breast cancer patients comprising purify ABC MuC1 from pooled sera taken from 20 patients with advanced breast cancer using immunoaffinity chromatography with a monoclonal antibody B55 (see Example 1).

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It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the method of Snijdwint et al. to use the monoclonal antibody A76-A/C7 instead of 139H2 to isolate the MUC1 antigens from breast cancer cell, and further formulate the MUC1 antigens in a pharmaceutically acceptable form or diagnostically applicable form in view of Ryuko, Chu and Robertson et al. One would have been motivated to do so because Ryuko et al. disclose that both A76-A/C7 and 139H2 bind to the same epitope of MUC1 and have similar reactivity patterns with a variety of synthetic non-glycosylated and glycosylated MUC1 peptides, and both antibodies react with all the MUC-1 expressing cancer cell lines. It would have been obvious to simply substitute one known, equivalent element for another to obtain predictable results. Moreover, one would have been motivated to formulate the MUC1 antigens in a pharmaceutically acceptable form or diagnostically applicable form for the purpose of treating and diagnosing MUC-1 expressing cancer. One of ordinary skill in the art would have a reasonable expectation of success to modify the method of Snijdwint et al. to use the monoclonal antibody A76-A/C7 instead of 139H2 to isolate the MUC1 antigens from breast cancer cell, and further formulate the MUC1 antigens in a pharmaceutically acceptable form or diagnostically applicable form because Snijdwint et al. teach a method of isolation of MUC1 antigens using a monoclonal antibody, and the methods of formulation of tumor antigens in a pharmaceutically acceptable form or diagnostically applicable form were well known in the art as shown by the teaching of Chu and Robertson.

Conclusion

21. No claims are allowed.
22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HONG SANG whose telephone number is (571)272-8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hong Sang/
Examiner, Art Unit 1643
10/23/2008